

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

January 12, 2005

Item: Nellcor pulse oximeters, model 595 and limited quantities of models 395, 295 and 290. Affected units were manufactured after November 8, 2001. Nellcor notified known affected customers by letter dated October 18, 2004 (Attachment 1).

Specific Incident: Alarm speakers and other audio notifications are reported to fail at a higher rate than expected. While the reported failure rate is low and no other features are affected (visual, remote alarms, etc.), failure could result in serious patient injury, depending upon the specific application of the pulse oximeter. Nellcor will replace affected speaker assemblies (see Attachment 2 for details).

Action:

1. Immediately (within the next 48 hours) determine and identify all affected units. Only units manufactured after November 8, 2001 (after S/N G01844386) are affected.
2. Until the speaker assemblies are replaced, users should routinely test speaker functions by:
 - a. Listening for the tone emitted during the Power On Test.
 - b. Activating audio pulse tones while monitoring patients to hear patient's pulse to provide positive confirmation of speaker function; volume can be set low to minimize disturbing patients.
3. Ensure user and Biomedical Engineering inspections include alarm testing according to manufacturer recommendations.
4. If the speaker fails, immediately remove the unit from service and replace with another unit, making sure the speaker is functioning on the replacement unit. Contact Nellcor at the phone numbers listed below and see the attached for replacement speakers and/or service.

Add'l. Information: Due to the large number of affected pulse oximeters, speaker replacement will take several months to complete.
Operator and service manuals are available on Nellcor's website:
http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/productmanuals.html
Also, please contact the VA Center for Engineering Occupational Safety & Health (CEOSH) at (314) - 543-6700 if you are affected and did not receive Nellcor's letter.

Source: CEOSH and Manufacturer

Contact: Nellcor Technical Support at (800) - 635-5267 (Option 1 – Customer Service, Option 3 – Technical Service)
You can also contact Paul Sherman, CEOSH at (314) - 543-6700



4280 Hacienda Drive
Pleasanton, CA 94588

Tele: 925 463-4000
Fax: 925 463-4420

Nellcor

October 18, 2004

AUDIO ALARM ADVISORY

Dear Valued Nellcor Customer:

As part of Nellcor's standard quality activities, our analysis of service data has indicated that the speaker component used in the *Nellcor*® N-595 pulse oximeter, and in limited units of the N-395, NPB-290 and NPB-295 pulse oximeters (after serial number G01844386), is experiencing a failure rate which is slightly higher than has been typical with other speakers. In isolated instances when the failure mode is present, the audio alarm of the unit may not sound. The rate of failures is extremely low (less than two tenths of one percent of the installed instrument base have experienced the failure), and neither visual nor remote alarm functions, nor other device features are affected. However, we felt it was important for us to bring this to your attention, because of our shared interest in patient safety, so that we could remind you of various practices you can follow to ensure the appropriate operation of audio alarms and to mitigate the risks of alarm speaker failure.

1. **Utilize self-testing alarm system functions:** The *Nellcor* N-595, N-395, NPB-290, and NPB-295 all feature a Power-On-Self-Test (POST). This POST test, which is described in our Operator's Manual, forces the monitor to emit an audible tone when powered on. We recommend you confirm that your staff is trained to recognize this tone and to check to determine that it is present when initiating monitoring on patients.
2. **Test alarm systems while in use:** We recommend that your staff routinely check monitor alarms to ensure that they are set appropriately and are functional, at an interval defined by your facility. We concur with JCAHO's recommendation that healthcare organizations should establish routine preventative maintenance programs for all monitoring equipment, and further believe that verification of alarm operation to be an important part of any such program. Many healthcare facilities utilize policies that instruct their staff to check alarms when assuming responsibility for a patient, and you may wish to consider implementing similar practices if not already present. For instructions on how to check alarm volume and other functions, please refer to the enclosed Quick Guides or the monitor's Operator's Manual, or contact Nellcor Technical Services department.

Please note that in the next few weeks we will make available an optional adhesive sticker that can be applied to the monitor as a reminder to periodically perform an alarm check. The optional alarm reminder sticker can be obtained at no charge by contacting our Customer Service or Technical Services departments at the number listed below.

3. **Utilize pulse tones when monitoring:** Nellcor pulse oximeters feature an audio pulse tone when the patient's pulse is detected, and pulse tone volume is set at a level to be audible. The presence of a pulse tone indicates the monitor's audio circuit is functional. Distortions and/or the absence of pulse tones may indicate audio difficulties, and alert users to a potential problem.

October 18, 2004

4. **Consider use of remote alarm annunciation:** The *Nellcor* N-595, N-395, NPB-290, and NPB-295 all feature the ability to be connected to nurse call systems for remote annunciation of monitor alarms. Remote annunciation is an important feature for complying with JCAHO's current directive that monitor alarms must be of sufficient magnitude to be heard throughout the care unit. Remote annunciation of alarms also provides greater confidence that an alarm will be heard. In the event of a speaker failure, serial port alarm status messages and/or nurse call functions will continue to be sent, thus alerting staff.
5. **Service resources:** If your facility determines, by any means, that a Nellcor monitor's alarms are not working appropriately, please contact Nellcor Technical Services at 1-800-635-5267, option 3. Technical Services can provide troubleshooting assistance, and help in the identification of spare parts. We also make our monitor Operators and Service Manuals available 24 hours a day via our website. For a free download from our website, manuals may be accessed at:

http://www.mallinckrodt.com/respiratory/resp/serv_supp/productmanuals.html

If you are unable to access our website, you can contact either our Customer Service or Technical Services departments by calling toll free 1-800-635-5267 (Option 1 for Customer Service or Option 3 for Technical Services).

We are committed to continuous quality improvement. We are actively investigating this matter and are working to provide you with a timely solution. If you have questions regarding this matter, please call Nellcor Technical Services or your local Nellcor Sales Representative.




Sincerely,

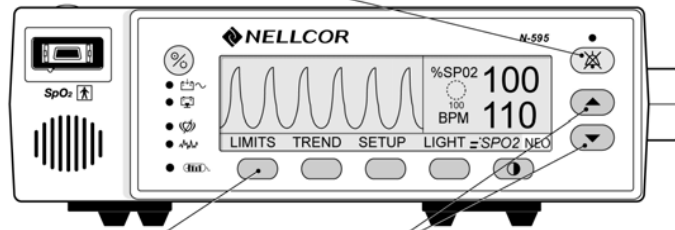
A handwritten signature in black ink, appearing to read "Kent W. Jones". The signature is fluid and cursive, with the first name "Kent" being the most prominent.

Kent W. Jones
Vice President
Quality Assurance & Regulatory Affairs

N-595 Alarms Quick Reference

ALARM VOLUME: Press and hold  until "VOL" appears, then  or 

ALARM SILENCE DURATION: Press and hold  until "SEC" appears, then  or 




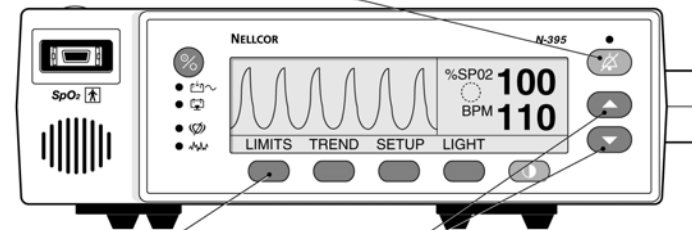
PULSE BEEP VOLUME: Press  or 

ALARM LIMITS: Press . Use  to select parameter, then  or 

N-395 Alarms Quick Reference

ALARM VOLUME: Press and hold  until "VOL" appears, then  or 



ALARM SILENCE DURATION: Press and hold  until "SEC" appears, then  or 




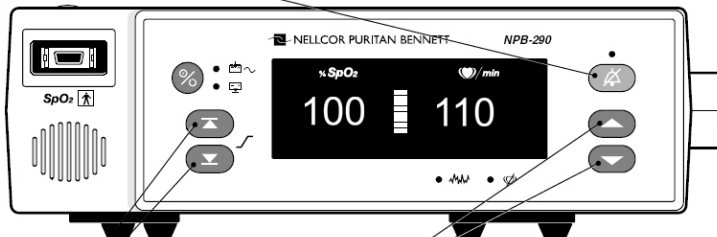
PULSE BEEP VOLUME: Press  or 

ALARM LIMITS: Press . Use  to select parameter, then  or 

NPB-290 Alarms Quick Reference

ALARM VOLUME: Press and hold  until "VOL" appears, then  or 

ALARM SILENCE DURATION: Press and hold  until "SEC" appears, then  or 



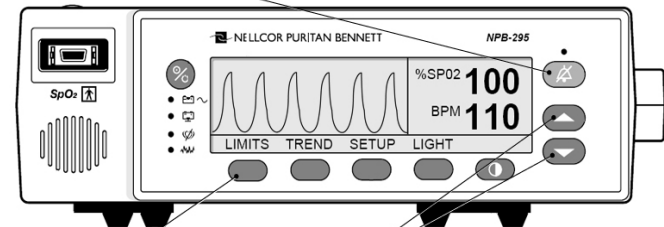
PULSE BEEP VOLUME: Press  or 

ALARM LIMITS: Press  or  to select parameter, then  or 

NPB-295 Alarms Quick Reference

ALARM VOLUME: Press and hold  until "VOL" appears, then  or 

ALARM SILENCE DURATION: Press and hold  until "SEC" appears, then  or 



PULSE BEEP VOLUME: Press  or 

ALARM LIMITS: Press . Use  to select parameter, then  or 



4280 Hacienda Drive
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December 8, 2004

AUDIO ALARM UPDATE

Dear Valued Nellcor Customer:

This letter is an important update to our October 18, 2004 letter regarding the speaker component used in the *Nellcor*® N-595 pulse oximeter, and in limited units of the N-395, NPB-290 and NPB-295 pulse oximeters (after serial number G01844386). We are pleased to inform you that we have identified and validated an alternative speaker assembly, and will be contacting all affected customers of record over the next several months to offer speaker assembly upgrades for affected monitors. Due to the large number of units involved in this upgrade program, it will take some time to produce the full supply of replacement speaker assemblies. Therefore, we will need to schedule upgrades in advance. Our staff will be pleased to provide you more details regarding this upgrade when your facility is contacted.

We are also pleased to inform you that an optional adhesive sticker, that can be applied to the monitor as a reminder to periodically perform an alarm check, is now available. The optional alarm reminder sticker can be obtained at no charge by contacting our Customer Service or Technical Services departments at 1-800-635-5267.

As this issue does not appear isolated to a specific batch or lot of this particular speaker assembly, we wish all customers who have received N-595, N-395, NPB-290 and NPB-295 pulse oximeters after serial number G01844386 to be aware of this upgrade option. Please forward a copy of this letter to anyone to whom you may have distributed any of the affected monitors identified above.

For your convenient reference, we have included a copy of our October 18, 2004 letter, which discusses several practices you can follow to ensure the appropriate operation of audio alarms and to mitigate the risks of alarm speaker failure.

We remain committed to continuous quality improvement, and continue to work diligently to make upgrades available as soon as possible. If you have questions regarding this matter, please contact Technical Services at 1-800-635-5267, press 3, or your local Nellcor Sales Representative.

Sincerely,

A handwritten signature in black ink, which appears to read "Kent W. Jones".

Kent W. Jones
Vice President
Quality Assurance & Regulatory Affairs